

CLAIMS

We claim:

1. A suppository composition for rectal administration of a lincosamide  
antibacterial drug, comprising an antimicrobially effective amount of the lincosamide  
5 dispersed in a Hard Fat suppository base, wherein the lincosamide is in the form of  
solid particles.
2. The composition of claim 1, wherein the lincosamide is present in a form  
selected from the group consisting of a lincosamide salt and a lincosamide ester.
- 10 3. The composition of claim 1, wherein the lincosamide is present in the form of  
a lincosamide phosphate.
4. The composition of claim 1 wherein the lincosamide is present in said  
15 composition in an amount from about 0.1 % by weight of the entire composition to  
about 60% by weight of the entire composition.
5. The composition of claim 1 wherein the lincosamide is selected from the  
group consisting of pirlimycin and lincomycin.
- 20 6. The composition of claim 1 wherein the lincosamide is clindamycin.
- Sub  
A17* 7. The composition of claim 6 wherein said composition contains 50 to 150 mg  
of the clindamycin is present in said composition in an amount from about 1.5 % by  
25 weight of the entire composition to about 7.5% by weight of the entire composition.
8. The composition of claim 1 wherein said Hard Fat has a  $\beta$  polymorphic form  
which has a flow point in the range from 30 °C to 40 °C.
- 30 9. The composition of claim 1 wherein said Hard Fat has a  $\beta$  polymorphic form  
which has a flow point of 37 °C or less.

10. The composition of claim 1 wherein the Hard Fat is a mixture of glyceride esters of vegetable  $C_{12}$ - $C_{18}$  saturated fatty acids containing at least about 50% triglyceride esters.

11. The composition of claim 1 wherein the particles of lincosamide have particle size of  $10\mu\text{m}$  or less.

12. The composition of claim 1 wherein the Hard Fat base is a Hard Fat NF suppository base having the following properties:

10	Open-tube melting point:	31.0-33.0 °C ( $\alpha$ polymorphic form)
	Solidification point:	30.0-32.5 °C ( $\alpha$ polymorphic form)
	Hydroxyl value	max. 3 mg potassium hydroxide/g
	Saponification value:	240-250 mg potassium hydroxide/g
	Diglycerides	max. 15% by weight
15	Monoglycerides	max 1% by weight.

13. A method of rectally administering a lincosamide to a subject, comprising the steps of:

- 20 a) providing a suppository comprising an antimicrobially effective amount of the lincosamide, dispersed in a Hard Fat suppository base, wherein the lincosamide is in the form of particles, wherein the suppository is sufficiently small to pass through the anus of the subject; and
- b) inserting the rectal suppository into the rectum of the subject, through the anus.

14. The method of claim 13, wherein the subject is a mammal.

15. The method of claim 14, wherein the mammal is selected from the group consisting of a dog, a cat, a sheep, a cow, a steer, a goat, and a horse.

16. The method of claim 14, wherein the mammal is a human being.

17. The method of claim 13 wherein the lincosamide is selected from the group consisting of lincomycin and pirlimycin.

18. The method of claim 13 wherein the lincosamide is a clindamycin.

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19. The method of claim 13, wherein the lincosamide is present in a form selected from the group consisting of a lincosamide salt and a lincosamide ester.

20. The method of claim 13, wherein the lincosamide is present in the form of a lincosamide phosphate.

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21. The method of claim 13, wherein the lincosamide is present in the suppository in an amount from about 0.1 % by weight to about 60% by weight of the entire composition.

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22. The method of claim 13 wherein said Hard Fat has a  $\beta$  polymorphic form which has a flow point in the range from 30 °C to 40 °C.

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23. The method of claim 13 wherein said Hard Fat has a  $\beta$  polymorphic form which has a flow point of about 37 °C or less.

24. The method of claim 13 wherein the Hard Fat is a mixture of glyceride esters of vegetable C<sub>12</sub>-C<sub>18</sub> saturated fatty acids containing at least about 50% triglyceride esters.

25. The method of claim 13 wherein the lincosamide has a particle size of 10  $\mu$ m or less.

26. The method of claim 13 wherein the Hard Fat base is a Hard Fat NF suppository base having the following properties:

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Open-tube melting point: 31.0-33.0 °C ( $\alpha$  polymorphic form)

Solidification point: 30.0-32.5 °C ( $\alpha$  polymorphic form)

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Hydroxyl value	max. 3 mg potassium hydroxide/g
Saponification value:	240-250-mg-potassium-hydroxide/g
Diglycerides	max. 15% by weight
Monoglycerides	max 1% by weight.

27. A method of treating a mammalian subject infected with at least one gram-positive, comprising the steps of:

- a) providing a suppository comprising an antimicrobially effective amount of the lincosamide, dispersed in a Hard Fat suppository base, wherein the lincosamide is in the form of particles, wherein the suppository is sufficiently small to pass through the anus of the subject;
- b) inserting the rectal suppository into the rectum of the subject, through the anus; and
- c) repeating step (b) until the subject is cured of the infection.

28. The method of claim 27, wherein the mammal is a human being.

29. The method of claim 27 wherein the lincosamide is selected from the group consisting of lincomycin and pirlimycin.

30. The method of claim 27 wherein the lincosamide is a clindamycin.

31. The method of claim 27, wherein the lincosamide is present in a form selected from the group consisting of a lincosamide salt and a lincosamide ester.

32. The method of claim 27, wherein the lincosamide is present in the form of a lincosamide phosphate.

33. The method of claim 27 wherein the Hard Fat has a  $\beta$  polymorphic form which has a flow point in the range from 30 °C to 40 °C.

34. The method of claim 27 wherein the Hard Fat is a mixture of glyceride esters of vegetable-C<sub>12</sub>-C<sub>18</sub>-saturated fatty acids containing at least about 50% triglyceride esters.

35. The method of claim 27 wherein the lincosamide has a particle size of 10 $\mu$ m or less.

36. The method of claim 27 wherein the Hard Fat base is a Hard Fat NF suppository base having the following properties:

10	Open-tube melting point:	31.0-33.0 °C ( $\alpha$ polymorphic form)
	Solidification point:	30.0-32.5 °C ( $\alpha$ polymorphic form)
	Hydroxyl value	max. 3 mg potassium hydroxide/g
	Saponification value:	240-250 mg potassium hydroxide/g
	Diglycerides	max. 15% by weight
15	Monoglycerides	max 1% by weight.

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